UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,739	03/27/2006	Makoto Noami	2006_0106A	7704

513 7590 09/22/2011

WENDEROTH, LIND & PONACK, L.L.P.
1030 15th Street, N.W.,
Suite 400 East
Washington, DC 20005-1503

EXAMINER	
BUIE-HATCHER, NICOLE M	

ART UNIT	PAPER NUMBER
1767	

NOTIFICATION DATE	DELIVERY MODE
09/22/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com
eoa@wenderoth.com

Office Action Summary	Application No.	Applicant(s)	
	10/567,739	NOAMI ET AL.	
	Examiner	Art Unit	
	NICOLE M. BUIE-HATCHER	1767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *12,14,22,29,30 and 32-54* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *12,14,22,29,30 and 32-54* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 09/08/2011 has been entered.

Response to Amendment

The amendment filed 09/08/2011 has been entered. **Claims 12, 14, 22, 29, 32, and 33** remain pending. **Claims 34-54** have been added.

Information Disclosure Statement

The information disclosure statement filed 02/10/2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. There is no copy of the foreign document, JP 2003-509339 A.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12, 30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1).

Regarding claims 12 and 30, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol (PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, an aqueous solution is prepared. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed

PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts, wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range. Hoshi et al. discloses the amount of PVA and/or derivative is from 50 to 90 wt% and the amount of the polymerizable vinyl monomers is from 10 to 50 wt% [0034]. The amount of monomer (1) which includes acrylic acid is from 50 to 95 wt% relative to the total amount of the polymerizable vinyl monomers; the amount of monomer (2) which includes methyl methacrylate is from 60 to 90 wt% relative to the total amount of the polymerizable vinyl monomers [0036]. (Based on calculations, the weight ratio of the partially hydrolyzed polyvinyl alcohol, the methyl methacrylate and the acrylic acid is 50-90:6-45:0.005-25 which overlaps the claimed range).

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

It would have been obvious to one of ordinary skill in the art at the time of invention to use the overlapping range of the weight ratio of the partially hydrolyzed polyvinyl alcohol, the methyl methacrylate and the acrylic acid, and the motivation to do so would have been as Hoshi et al. suggests such amounts would have been expected to have similar properties, including solubility, improved strength [0035]. It would have been obvious to one of ordinary skill in the art at the time of invention to have selected the overlapping portion of the ranges disclosed by the reference because overlapping ranges have been held to be a prima facie case of obvious. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05.

Regarding claim 32, Hoshi et al. discloses the hard capsule is used for drugs for medical treatment, drugs/chemicals for animals, plants, and foodstuffs [0048]. The hard capsule is a coating for these components. Regarding the instant claim, once the medicine, animal drug, agricultural chemical or food is coated the water present in the solution is removed. Therefore, this is a product-by-process claim. Regarding the method limitations, the examiner notes that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated *in Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. *In re Pilkington*, 411 F. 2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process). See MPEP § 2113.

Claims 14, 22, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1).

Regarding claims 14 and 22, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol (PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, an aqueous solution is prepared. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts, wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range.

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl

methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

Regarding claim 29, Hoshi et al. discloses the hard capsule is used for drugs for medical treatment, drugs/chemicals for animals, plants, and foodstuffs [0048]. The hard capsule is a coating for these components. Regarding the instant claim, once the medicine, animal drug, agricultural chemical or food is coated the water present in the solution is removed. Therefore, this is a product-by-process claim. Regarding the method limitations, the examiner notes that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated *in Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. *In re Pilkington*, 411 F. 2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process). See MPEP § 2113.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1).

Regarding claim 33, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol (PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, an aqueous solution is

prepared. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts, wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range.

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

However, Hoshi et al. does not disclose the aqueous solution is a binder solution. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See MPEP § 2111.02.

Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1).

Regarding claims 34 and 35, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol (PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts, wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range. Hoshi et al. discloses the amount of PVA and/or derivative is from 50 to 90 wt% and the amount of the polymerizable vinyl monomers is from 10 to 50 wt% [0034]. The amount of monomer (1) which includes acrylic acid is from 50 to 95 wt% relative to the total amount of the polymerizable vinyl monomers; the amount of monomer (2) which includes methyl methacrylate is from 60 to 90 wt% relative to the total amount of the polymerizable vinyl monomers [0036]. (Based on calculations, the weight ratio of the partially hydrolyzed polyvinyl alcohol, the methyl methacrylate and the acrylic acid is 50-90:6-45:0.005-25 which overlaps the claimed range). Hoshi et al. discloses the capsule is dispersed in water (suspension wherein the particles are dispersed in the water) [0035].

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

It would have been obvious to one of ordinary skill in the art at the time of invention to use the overlapping range of the weight ratio of the partially hydrolyzed polyvinyl alcohol, the methyl methacrylate and the acrylic acid, and the motivation to do so would have been as Hoshi et al. suggests such amounts would have been expected to have similar properties, including solubility, improved strength [0035]. It would have been obvious to one of ordinary skill in the art at the time of invention to have selected the overlapping portion of the ranges disclosed by the reference because overlapping ranges have been held to be a prima facie case of obvious. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05.

However, Hoshi et al. does not disclose an aqueous suspension of the composition. Okaya et al. teaches a process for the preparation of acrylate or methacrylate grafted solid materials, such as polyvinyl alcohol (Abstract, C1/L4-10). Okaya et al. teaches the

polymerization is conducted in an aqueous solution or suspension (C1/L69-C2/L11). Hoshi et al. and Okaya et al. are analogous art concerned with similar technical difficulty, namely methacrylate-grafted polyvinyl alcohols. It would have been obvious to one of ordinary skill in the art at the time of invention to use the aqueous suspension process per the teachings of Okaya et al. for the preparing the suspension of the composition of Okaya et al., and the motivation to do so would have been as Okaya et al. suggests the polymerization of the acrylic monomer to the polymer can be very smoothly carried out (C1/L69-C2/L11).

Regarding claim 36, Hoshi et al. discloses the hard capsule is used for drugs for medical treatment, drugs/chemicals for animals, plants, and foodstuffs [0048]. The hard capsule is a coating for these components. Regarding the instant claim, once the medicine, animal drug, agricultural chemical or food is coated the water present in the solution is removed. Therefore, this is a product-by-process claim. Regarding the method limitations, the examiner notes that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated *in Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. *In re Pilkington*, 411 F. 2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process). See MPEP § 2113.

Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1).

Regarding claims 37 and 38, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol (PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts, wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range. Hoshi et al. discloses a publicly known method can be used as the method of copolymerization [0037]. Hoshi et al. discloses the capsule is dispersed in water (suspension wherein the particles are dispersed in the water) [0035].

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl

methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

It would have been obvious to one of ordinary skill in the art at the time of invention to use the overlapping range of the weight ratio of the partially hydrolyzed polyvinyl alcohol, the methyl methacrylate and the acrylic acid, and the motivation to do so would have been as Hoshi et al. suggests such amounts would have been expected to have similar properties, including solubility, improved strength [0035]. It would have been obvious to one of ordinary skill in the art at the time of invention to have selected the overlapping portion of the ranges disclosed by the reference because overlapping ranges have been held to be a prima facie case of obvious. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05.

Regarding claim 39, Hoshi et al. discloses the hard capsule is used for drugs for medical treatment, drugs/chemicals for animals, plants, and foodstuffs [0048]. The hard capsule is a coating for these components. Regarding the instant claim, once the medicine, animal drug, agricultural chemical or food is coated the water present in the solution is removed. Therefore, this is a product-by-process claim. Regarding the method limitations, the examiner notes that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated *in Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. *In re Pilkington*, 411 F. 2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process

claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process). See MPEP § 2113.

Claims 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1).

Regarding claims 40, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol (PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts, wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range. Hoshi et al. discloses the capsule is dispersed in water (suspension wherein the particles are dispersed in the water) [0035].

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

It would have been obvious to one of ordinary skill in the art at the time of invention to use the overlapping range of the weight ratio of the partially hydrolyzed polyvinyl alcohol, the methyl methacrylate and the acrylic acid, and the motivation to do so would have been as Hoshi et al. suggests such amounts would have been expected to have similar properties, including solubility, improved strength [0035]. It would have been obvious to one of ordinary skill in the art at the time of invention to have selected the overlapping portion of the ranges disclosed by the reference because overlapping ranges have been held to be a prima facie case of obvious. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05.

However, Hoshi et al. does not disclose the aqueous dispersion is a binder dispersion or suspension. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See MPEP § 2111.02.

Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1) in view of Fujita et al. (US 4,320,040).

Regarding claims 41 and 42, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol (PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts, wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range. Hoshi et al. discloses the amount of PVA and/or derivative is from 50 to 90 wt% and the amount of the polymerizable vinyl monomers is from 10 to 50 wt% [0034]. The amount of monomer (1) which includes acrylic acid is from 50 to 95 wt% relative to the total amount of the polymerizable vinyl monomers; the amount of monomer (2) which includes methyl methacrylate is from 60 to 90 wt% relative to the total amount of the polymerizable vinyl monomers [0036]. (Based on calculations, the weight ratio of the partially hydrolyzed polyvinyl alcohol, the methyl methacrylate and the acrylic acid is 50-90:6-45:0.005-25 which overlaps the claimed range). Hoshi et al. discloses a publicly known method can be used as the method of polymerization or copolymerization [0037].

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so

would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

It would have been obvious to one of ordinary skill in the art at the time of invention to use the overlapping range of the weight ratio of the partially hydrolyzed polyvinyl alcohol, the methyl methacrylate and the acrylic acid, and the motivation to do so would have been as Hoshi et al. suggests such amounts would have been expected to have similar properties, including solubility, improved strength [0035]. It would have been obvious to one of ordinary skill in the art at the time of invention to have selected the overlapping portion of the ranges disclosed by the reference because overlapping ranges have been held to be a prima facie case of obvious. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05.

However, Hoshi et al. does not disclose the composition contains an organic solvent. Fujita et al. teaches emulsion or suspension polymerization wherein polymers are obtained by polymerizing acrylic acid and/or methacrylic acid in an aqueous solution of polyvinylalcohol dispersed in a water-insoluble organic solvent (C3/L6-23). In Example 3, toluene is used in the polymerization process. Dispersion stabilizers and surface active agents are used together (C3/L6-23). With emulsion polymerization, the resulting polymer is dispersed in the

polymerization medium. Hoshi et al. and Fujita et al. are analogous art concerned with similar technical difficulty, namely polymerization of PVA with acrylic acid and/or methacrylic acid. It would have been obvious to one of ordinary skill in the art at the time of invention to use the technique of polymerization per the teachings of Fujita et al. to prepare the polymer of Hoshi et al. in order to obtain a composition containing an organic solvent, and the motivation to do so would have been as Fujita et al. suggests such polymerization techniques are applied to polymerize acrylic acid and/or methacrylic acid in the presence of polyvinyl alcohol in an aqueous medium with a reasonable expectation of success (C3/L6-23).

However, Hoshi et al. does not disclose an organic solution of the copolymer. The Office realizes that all of the claimed effects or physical properties are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients, claimed amounts, and substantially similar process of making. According to the original specification, it is the PVA copolymer which is soluble in a solvent (P2/L15-23). Therefore, the claimed effects and physical properties, i.e. an organic solution of the copolymer would implicitly be achieved by a composition with all the claimed ingredients, claimed amounts, and substantially similar process of making. See MPEP § 2112.01. If it is the applicant's position that this would not be the case: (1) evidence would need to be provided to support the applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties with only the claimed ingredients, claimed amounts, and substantially similar process of making.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1).

Regarding claim 43, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol (PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts, wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range. Hoshi et al. discloses the hard capsule is used for drugs for medical treatment, drugs/chemicals for animals, plants, and foodstuffs [0048]. The hard capsule is a coating for these components. Regarding the instant claim, once the medicine, animal drug, agricultural chemical or food is coated the water present in the solution is removed. Therefore, this is a product-by-process claim.

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

It would have been obvious to one of ordinary skill in the art at the time of invention to use the overlapping range of the weight ratio of the partially hydrolyzed polyvinyl alcohol, the methyl methacrylate and the acrylic acid, and the motivation to do so would have been as Hoshi et al. suggests such amounts would have been expected to have similar properties, including solubility, improved strength [0035]. It would have been obvious to one of ordinary skill in the art at the time of invention to have selected the overlapping portion of the ranges disclosed by the reference because overlapping ranges have been held to be a prima facie case of obvious. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05.

Regarding the method limitations, the examiner notes that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated *in Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. *In re Pilkington*, 411 F. 2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process). See MPEP § 2113.

Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1) in view of Fujita et al. (US 4,320,040).

Regarding claims 44 and 45, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol (PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts, wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range. Hoshi et al. discloses a publicly known method can be used as the method of polymerization or copolymerization [0037].

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so

would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

However, Hoshi et al. does not disclose the composition contains an organic solvent. Fujita et al. teaches emulsion or suspension polymerization wherein polymers are obtained by polymerizing acrylic acid and/or methacrylic acid in an aqueous solution of polyvinylalcohol dispersed in a water-insoluble organic solvent not dissolving the produced polymer as a dispersion medium under stirring (C3/L6-23). Dispersion stabilizers and surface active agents are used together (C3/L6-23). With emulsion polymerization, the resulting polymer is dispersed in the polymerization medium. Hoshi et al. and Fujita et al. are analogous art concerned with similar technical difficulty, namely polymerization of PVA with acrylic acid and/or methacrylic acid. It would have been obvious to one of ordinary skill in the art at the time of invention to use the technique of polymerization per the teachings of Fujita et al. to prepare the polymer of Hoshi et al. in order to obtain a composition containing an organic solvent, and the motivation to do so would have been as Fujita et al. suggests such polymerization techniques are applied to polymerize acrylic acid and/or methacrylic acid in the presence of polyvinyl alcohol in an aqueous medium with a reasonable expectation of success (C3/L6-23).

However, Hoshi et al. does not disclose an organic solution of the copolymer. The Office realizes that all of the claimed effects or physical properties are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients, claimed amounts, and substantially similar process of making. According to the original specification, it is the PVA copolymer which is soluble in a solvent (P2/L15-23). Therefore, the claimed effects and

physical properties, i.e. an organic solution of the copolymer would implicitly be achieved by a composition with all the claimed ingredients, claimed amounts, and substantially similar process of making. See MPEP § 2112.01. If it is the applicant's position that this would not be the case: (1) evidence would need to be provided to support the applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties with only the claimed ingredients, claimed amounts, and substantially similar process of making.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1).

Regarding claim 46, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol (PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts, wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range. Hoshi et al. discloses the hard capsule is used for drugs for

medical treatment, drugs/chemicals for animals, plants, and foodstuffs [0048]. The hard capsule is a coating for these components. Regarding the instant claim, once the medicine, animal drug, agricultural chemical or food is coated the water present in the solution is removed. Therefore, this is a product-by-process claim.

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

It would have been obvious to one of ordinary skill in the art at the time of invention to use the overlapping range of the weight ratio of the partially hydrolyzed polyvinyl alcohol, the methyl methacrylate and the acrylic acid, and the motivation to do so would have been as Hoshi et al. suggests such amounts would have been expected to have similar properties, including solubility, improved strength [0035]. It would have been obvious to one of ordinary skill in the art at the time of invention to have selected the overlapping portion of the ranges disclosed by the reference because overlapping ranges have been held to be a prima facie case of obvious. *In*

re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05.

Regarding the method limitations, the examiner notes that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated *in Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. *In re Pilkington*, 411 F. 2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process). See MPEP § 2113.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1) in view of Fujita et al. (US 4,320,040).

Regarding claim 47, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol (PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts,

wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range. Hoshi et al. discloses a publicly known method can be used as the method of polymerization or copolymerization [0037].

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

However, Hoshi et al. does not disclose the composition contains an organic solvent. Fujita et al. teaches emulsion or suspension polymerization wherein polymers are obtained by polymerizing acrylic acid and/or methacrylic acid in an aqueous solution of polyvinylalcohol dispersed in a water-insoluble organic solvent (C3/L6-23). In Example 3, toluene is used. Dispersion stabilizers and surface active agents are used together (C3/L6-23). Hoshi et al. and Fujita et al. are analogous art concerned with similar technical difficulty, namely polymerization of PVA with acrylic acid and/or methacrylic acid. It would have been obvious to one of ordinary skill in the art at the time of invention to use the technique of polymerization per the

teachings of Fujita et al. to prepare the polymer of Hoshi et al. in order to obtain a composition containing an organic solvent, and the motivation to do so would have been as Fujita et al. suggests such polymerization techniques are applied to polymerize acrylic acid and/or methacrylic acid in the presence of polyvinyl alcohol in an aqueous medium with a reasonable expectation of success (C3/L6-23).

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1).

Regarding claim 50, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol (PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts, wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range. Hoshi et al. discloses the hard capsule is used for drugs for medical treatment, drugs/chemicals for animals, plants, and foodstuffs [0048]. The hard capsule is a coating for these components. Regarding the instant claim, once the medicine, animal drug,

agricultural chemical or food is coated the water present in the solution is removed. Therefore, this is a product-by-process claim.

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

It would have been obvious to one of ordinary skill in the art at the time of invention to use the overlapping range of the weight ratio of the partially hydrolyzed polyvinyl alcohol, the methyl methacrylate and the acrylic acid, and the motivation to do so would have been as Hoshi et al. suggests such amounts would have been expected to have similar properties, including solubility, improved strength [0035]. It would have been obvious to one of ordinary skill in the art at the time of invention to have selected the overlapping portion of the ranges disclosed by the reference because overlapping ranges have been held to be a prima facie case of obvious. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05.

Regarding the method limitations, the examiner notes that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated *in Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. *In re Pilkington*, 411 F. 2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process). See MPEP § 2113.

Claims 48 and 49are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1) in view of Fujita et al. (US 4,320,040).

Regarding claims 48 and 49, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol (PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts, wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the

claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range. Hoshi et al. discloses the amount of PVA and/or derivative is from 50 to 90 wt% and the amount of the polymerizable vinyl monomers is from 10 to 50 wt% [0034]. The amount of monomer (1) which includes acrylic acid is from 50 to 95 wt% relative to the total amount of the polymerizable vinyl monomers; the amount of monomer (2) which includes methyl methacrylate is from 60 to 90 wt% relative to the total amount of the polymerizable vinyl monomers [0036]. (Based on calculations, the weight ratio of the partially hydrolyzed polyvinyl alcohol, the methyl methacrylate and the acrylic acid is 50-90:6-45:0.005-25 which overlaps the claimed range). Hoshi et al. discloses a publicly known method can be used as the method of polymerization or copolymerization [0037].

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

It would have been obvious to one of ordinary skill in the art at the time of invention to use the overlapping range of the weight ratio of the partially hydrolyzed polyvinyl alcohol, the

methyl methacrylate and the acrylic acid, and the motivation to do so would have been as Hoshi et al. suggests such amounts would have been expected to have similar properties, including solubility, improved strength [0035]. It would have been obvious to one of ordinary skill in the art at the time of invention to have selected the overlapping portion of the ranges disclosed by the reference because overlapping ranges have been held to be a prima facie case of obvious. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05.

However, Hoshi et al. does not disclose the composition as an organic solvent dispersion. Fujita et al. teaches emulsion or suspension polymerization wherein polymers are obtained by polymerizing acrylic acid and/or methacrylic acid in an aqueous solution of polyvinylalcohol dispersed in a water-insoluble organic solvent not dissolving the produced polymer as a dispersion medium under stirring (C3/L6-23). Dispersion stabilizers and surface active agents are used together (C3/L6-23). With emulsion polymerization, the resulting polymer is dispersed in the polymerization medium. Hoshi et al. and Fujita et al. are analogous art concerned with similar technical difficulty, namely polymerization of PVA with acrylic acid and/or methacrylic acid. It would have been obvious to one of ordinary skill in the art at the time of invention to use the technique of polymerization per the teachings of Fujita et al. to prepare the polymer of Hoshi et al. in order to obtain an organic solvent dispersion, and the motivation to do so would have been as Fujita et al. suggests such polymerization techniques are applied to polymerize acrylic acid and/or methacrylic acid in the presence of polyvinyl alcohol in an aqueous medium with a reasonable expectation of success (C3/L6-23).

Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1) in view of Fujita et al. (US 4,320,040).

Regarding claims 51 and 52, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol (PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts, wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range. Hoshi et al. discloses a publicly known method can be used as the method of polymerization or copolymerization [0037].

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl

methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

However, Hoshi et al. does not disclose the composition as an organic solvent dispersion. Fujita et al. teaches emulsion or suspension polymerization wherein polymers are obtained by polymerizing acrylic acid and/or methacrylic acid in an aqueous solution of polyvinylalcohol dispersed in a water-insoluble organic solvent not dissolving the produced polymer as a dispersion medium under stirring (C3/L6-23). Dispersion stabilizers and surface active agents are used together (C3/L6-23). With emulsion polymerization, the resulting polymer is dispersed in the polymerization medium. Hoshi et al. and Fujita et al. are analogous art concerned with similar technical difficulty, namely polymerization of PVA with acrylic acid and/or methacrylic acid. It would have been obvious to one of ordinary skill in the art at the time of invention to use the technique of polymerization per the teachings of Fujita et al. to prepare the polymer of Hoshi et al. in order to obtain an organic solvent dispersion, and the motivation to do so would have been as Fujita et al. suggests such polymerization techniques are applied to polymerize acrylic acid and/or methacrylic acid in the presence of polyvinyl alcohol in an aqueous medium with a reasonable expectation of success (C3/L6-23).

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1).

Regarding claim 53, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol (PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-

modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts, wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range. Hoshi et al. discloses the hard capsule is used for drugs for medical treatment, drugs/chemicals for animals, plants, and foodstuffs [0048]. The hard capsule is a coating for these components. Regarding the instant claim, once the medicine, animal drug, agricultural chemical or food is coated the water present in the solution is removed. Therefore, this is a product-by-process claim.

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

It would have been obvious to one of ordinary skill in the art at the time of invention to use the overlapping range of the weight ratio of the partially hydrolyzed polyvinyl alcohol, the methyl methacrylate and the acrylic acid, and the motivation to do so would have been as Hoshi et al. suggests such amounts would have been expected to have similar properties, including solubility, improved strength [0035]. It would have been obvious to one of ordinary skill in the art at the time of invention to have selected the overlapping portion of the ranges disclosed by the reference because overlapping ranges have been held to be a prima facie case of obvious. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05.

Regarding the method limitations, the examiner notes that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated *in Thorpe*, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. *In re Pilkington*, 411 F. 2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process). See MPEP § 2113.

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoshi et al. (US 2003/0166763 A1) in view of Fujita et al. (US 4,320,040).

Regarding claim 54, Hoshi et al. discloses a copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinylalcohol

(PVA) and/or a derivative thereof (The unmodified PVA, amine-modified PVA, ethylene-modified PVA which are not a thiol-modified PVA can be used.) [0003, 0025]. In Synthesis Example 4, an unmodified PVA is used. In Synthesis Example 1, the PVA has a degree of polymerization of 500 which is within the claimed range, and the degree of hydrolysis is 88% (partially hydrolyzed PVA). For E-1002 shown in Table 1, the amount of (1) (which includes acrylic acid) [0033] is 6 weight parts and the amount of (2), methyl methacrylate is 14 parts, wherein the ratio of methyl methacrylate and acrylic acid is 3:7 which is within the claimed range. Also in E-1002, the weight ratio of PVA to the polymerizable vinyl monomer is 4:1 which is within the claimed range. Hoshi et al. discloses a publicly known method can be used as the method of polymerization or copolymerization [0037].

Regarding the PVA excluding a thiol-modified PVA, it would have been obvious to one of ordinary skill in the art at the time of invention to use an unmodified PVA, amine-modified PVA, or ethylene-modified PVA which are not thiol-modified PVA, and the motivation to do so would have been as Hoshi et al. suggests such PVAs are useful for preparing the hard capsule which possesses excellent water solubility [0003].

Regarding the use of acrylic acid as (1), it would have been obvious to one of ordinary skill in the art at the time of invention to use acrylic acid as (1), and the motivation to do so would have been as Hoshi et al. suggests, acrylic acid or methacrylic acid and methyl methacrylate are used [0033] to prepare a copolymer with excellent stability and water solubility [0003].

However, Hoshi et al. does not disclose the composition as an organic solvent dispersion. Fujita et al. teaches emulsion or suspension polymerization wherein polymers are obtained by

polymerizing acrylic acid and/or methacrylic acid in an aqueous solution of polyvinylalcohol dispersed in a water-insoluble organic solvent not dissolving the produced polymer as a dispersion medium under stirring (C3/L6-23). With emulsion polymerization, the resulting polymer is dispersed in the polymerization medium. Dispersion stabilizers and surface active agents are used together (C3/L6-23). Hoshi et al. and Fujita et al. are analogous art concerned with similar technical difficulty, namely polymerization of PVA with acrylic acid and/or methacrylic acid. It would have been obvious to one of ordinary skill in the art at the time of invention to use the technique of polymerization per the teachings of Fujita et al. to prepare the polymer of Hoshi et al. in order to obtain an organic solvent dispersion, and the motivation to do so would have been as Fujita et al. suggests such polymerization techniques are applied to polymerize acrylic acid and/or methacrylic acid in the presence of polyvinyl alcohol in an aqueous medium with a reasonable expectation of success (C3/L6-23).

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

The following comment(s) apply:

A) The previous rejection of claims 28 and 31 under 35 U.S.C. 112, second paragraph is withdrawn in light of Applicant's amendment.

B) Applicant's argument that any terminology in the preamble limits the structure of the claimed invention must be treated as a claim limitation (page 10) is not persuasive. As shown above, Hoshi et al. discloses an aqueous solution as well as an aqueous dispersion. In regards to

the medicine, animal drug, agricultural chemical, fertilizer, or food being coated by the composition is a product by process. The determination of patentability is on the product itself not in the method in which the product is made.

C) Applicant's argument that claims 12 and 14 recite "a copolymer consisting of a hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500", the polymerizable vinyl monomer consists of acrylic acid and methyl methacrylate combined in a weight ratio of 3:7 to 0.5:9.5 in the copolymer", and " the partially hydrolyzed polyvinyl alcohol excludes a thiol-modified polyvinyl alcohol" (pages 10 and 11) is not persuasive. As shown above in claims 12 and 14 above, Hoshi et al. teaches the polymerization degree, ratio of the amount of the acrylic and methyl methacrylate, and the unmodified as well as amine- or ethylene-modified PVA can be used instead of a thiol-modified PVA.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Akasaki et al. (US 4,912,184) discloses a process of polymerizing monomers such as acrylic ester and methacrylic ester in organic solvents (C2/L24-62).

Imura et al. (US 4,102,946) teaches ethylene-vinyl acetate copolymers or saponified co-polymers carboxylated by copolymerizing an alpha,beta-unsaturated carboxylic acid and/or anhydride wherein the reaction is conducted in a heterogeneous state (Abstract).

Hoshi et al. (US 6,967,026 B2) teaches a hard capsule which is made mainly of a polymer or copolymer obtained by polymerizing or copolymerizing at least one polymerizable vinyl monomer in the presence of polyvinyl alcohol and/or derivative thereof (Abstract).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE M. BUIE-HATCHER whose telephone number is (571)270-3879. The examiner can normally be reached on Monday-Thursday with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571)272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NICOLE M BUIE-HATCHER/
Examiner, Art Unit 1767
9/13/2011